

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 07 September 2006 has been entered in full. Claims 3-10, 13-16, 21-40 have been cancelled and claims 2 and 11 have been amended.

Claims 1, 2, 11, 12, 17-20 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 11, and 12, drawn to a PEGylated FGF-21 compound comprising an FGF-21 compound covalently attached to at least one PEG molecule.

Group II, claim(s) 17-20, drawn to a method for treating a patient exhibiting obesity, type 2 diabetes, insulin resistance, hyperinsulinemia, glucose intolerance, hyperglycemia, or metabolic syndrome comprising administering to a patient an amount of a FGF-21 mutein.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-IV do not relate to a single general inventive concept because they lack the same or corresponding technical feature.

Claim 1 is directed to a PEGylated FGF-21 compound comprising an FGF-21 compound covalently attached to at least one PEG molecule, wherein each PEG is attached to the FGF-21 compound at a cysteine or lysine amino acid residue and wherein the PEGylated FGF-21 compound has extended time action compared to a non-PEGylated FGF-21 compound. Itoh et al. (US 2002/01164713 A1 now US 7,259,248 B2) teach a FGF-21 variant having polymers including polyethylene glycol (PEG) attached to one or more reactive amino acid side chains, wherein the amino acid residues are cysteines and lysines and wherein the pegylation of FGF-21 proteins provides increased half-life (column 5, line 66 to column 6, line 14). The prior art meets the limitations disclosed in claim 1. Thus Group I lacks novelty or inventive step and does not make a contribution over the prior art. Since the first claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed invention.

Under PCR Rule 13.1, the application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of amino acid residue for the attachment of a PEG molecule are as follows:

- a) D25
- b) D38
- c) L58
- d) K59
- e) P60
- f) K69
- g) D79
- h) H87
- i) E91
- j) E101
- k) D102
- l) L114
- m) L116
- n) K122
- o) R126
- p) P130
- q) P133

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r) P140C

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claim 2.

The following claim is generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the amino acid residues do not share a common structural or functional feature.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1647
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/Bridget E Bunner/
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